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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/619,137

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David M. Reilly

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/619,137	<b>Applicant(s)</b> REILLY, DAVID M.	
	<b>Examiner</b> ELIZABETH R. MACNEILL	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 29-31 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-18 and 31 is/are rejected.
- 7) ☒ Claim(s) 5, 29 and 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Objections*

1. Claim 29 is objected to because of the following informalities: claim 29 has the wrong status identifier in the amendment filed 4/11/08. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 6, 17-18, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Niehoff (US 5,662,612).

Niehoff teaches an injector system comprising:

A syringe (10), a plunger (12), an encoding device (physical indicia, see Claim 3);

An injector (Fig 2B) with a housing (40), a motor (98), controller (160), a sensor to read the encoding device (detector, Claim 3), a drive member (20), the drive member operable to automatically advance after the syringe is mounted on the injector (Col 3 line 48-Col 4 line 3); And a plunger engagement detection device (168).

As to claim 2,19 see Col 1 line 65; "Before an empty new syringe can be filled, it is necessary that the plunger be moved fully forward in the syringe so that the syringe can be filled by rearward retraction of the plunger"

As to claim 3,4,20 see Col 3 lines 48-61; "To operate effectively, the plunger drive controller must determine the location of the plunger 12 relative to the ends of the syringe 10... offset value may be automatically computed by detecting physical indicia on the syringe."

As to claim 16, see potentiometer 168.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niehoff as applied to claims above, and further in view of Bucchianeri (US 4,424,720).

Niehoff teaches a linear potentiometer which indicates when the drive member has progressed far enough to engage the plunger, which position is calculated using the encoded information on the syringe body. The drive member of Niehoff includes opposite sidewalls on 18. Fig 1A-1B. The plunger includes rearwardly projecting element 14.

Niehoff does not teach a light source and light sensor for detecting engagement of the plunger and drive member.

Bucchianeri teaches a syringe type injector with a plunger (11b) that is driven forward or backwards by a drive member (18). The plunger and drive member are coupled by

the crank arm (17). The crank arm-plunger engagement is monitored by light source and photo-electric sensor 28a on the drive member (Fig 2a,2). See Col 15.

The plunger and drive member system of Niehoff includes structural features which would allow a light sensor/source combination to function without altering the structures of the coupling. See Fig 1A, 18/14.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the light source/sensor of Bucchianeri with the injector syringe system of Niehoff in order to prevent inadvertent de-coupling of the syringe/driver and injection error. Regarding the limitation that the sensor is on the plunger (claim 11), this would have been obvious to one of ordinary skill in the art since it would involve mere reversal of the parts.

#### ***Allowable Subject Matter***

5. Claims 5, 29 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

2. Applicant's arguments filed 11 April 2008 have been fully considered but they are not persuasive.

35 USC 102(b): Applicant agrees that Niehoff teaches a potentiometer for determining the position of the plunger within the syringe (page 2). Niehoff further teaches that the CPU may automatically calculate the position of the plunger within the syringe PRIOR to injection and then advance the drive enough to engage the plunger (Col 3 line 48-Col 4

line 3). The "engagement device detection device" is therefore the CPU and potentiometer; when the potentiometer indicates that the drive member has traveled a certain distance the CPU recognizes that the plunger is engaged.

Claims 2 and 19: the indicia indicates the position of the syringe plunger which tells the user if the syringe is empty or not, then the CPU knows if the plunger must be fully advanced. Col 1 line 65.

Claims 3,4,20: the drive is stopped by the CPU because the CPU has previously calculated the position of the plunger.

35 USC 103(a): see comments above, and Col 3 line 48-Col 4 line 3, which discusses that the plunger extender detection occurs before injection. As to the light sensor, the two arms 18 of Niehoff act as the photoelectric sensor 28a and the post 14 acts the opaque flag 28c. No reversal of parts is needed. The rejection is maintained.

### ***Conclusion***

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767

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